Documentation Checklist

Document	Completed
Study-related	
Protocol	
Staffing plan, including multisite organization chart	
Recruitment plan	
Statistical analysis plan	
Budget	
Contractual documents (e.g., memorandum of understanding [MOU], reliance agreement)	
Electronic health record use plan and IT-facilitated updates as needed	
Study plan and timeline	
Communication plan	
Committee membership and meeting plan, including advisory and steering committees	
Manual of procedures	
Data coordinating activities (e.g., data dictionary, data quality assessment, data harmonization across sites)	
Patient recruitment and intervention materials	
Clinical staff training and intervention materials	
Interviewer/research staff training	
Vendor contracts	
Specimen management plan	
Site initiation plan	
Dissemination and sustainability plan	
Regulatory	
Data sharing plan including data use agreements between parties	
IRB review and approval	
Registry in ClinicalTrials.gov	
Informing participants; consent process and documentation	
Oversight	
Data and safety monitoring plan/committee	
Data management plan	
Quality management plan	

DeBar L, Jarvik JG, Tuzzio L, Vazquez M. Assessing Feasibility: Introduction. In: *Rethinking Clinical Trials: A Living Textbook of Pragmatic Clinical Trials*. Bethesda, MD: NIH Health Care Systems Research Collaboratory. Available at: http://www.rethinkingclinicaltrials.org.php56-29.ord1-1.websitetestlink.com/assessing-feasibility/assessing-feasibility-introduction/. Updated December 10, 2018.